

IN THE CLAIMS

1. (currently amended) A method for [the] diagnosis of male infertility, comprising:
[characterized by]

(a) detecting in a sample obtained from a male patient, wherein said male patient is suspected of suffering from infertility and has two alleles of the POLG gene encoding the catalytic subunit of mitochondrial DNA polymerase, the presence or absence of at least one [[a]] mutation [or mutations] in the trinucleotide (CAG) microsatellite repeat of one allele of the POLG gene [encoding the catalytic subunit of mitochondrial DNA polymerase in a biological sample] and

(b) detecting the presence or absence of at least one mutation in another allele of the POLG gene in said sample; wherein the presence of at least one mutation in both alleles of said POLG gene is indicative of male infertility.

2. (currently amended) A method of [for population-based] screening for genetic predisposition to male infertility, comprising: [characterized by]

(a) detecting in a sample obtained from a male patient, wherein said male patient is suspected of suffering from infertility and has two alleles of the POLG gene encoding the catalytic subunit of mitochondrial DNA polymerase, the presence or absence of at least one [[a]] mutation [or mutations] in the trinucleotide (CAG) microsatellite repeat of one allele of the POLG gene [encoding the catalytic subunit of mitochondrial DNA polymerase in a biological sample] and

(b) detecting the presence or absence of at least one mutation in another allele of the POLG gene in said sample; wherein the presence of at least one mutation in both alleles of said POLG gene is indicative of genetic predisposition to male infertility.

3. (currently amended) A method of claim 1, wherein [characterized in that the mutation or] mutations are located in both alleles of the POLG gene in the trinucleotide (CAG) microsatellite repeat of the POLG gene.

4. (currently amended) A method of claim 2 [[3]], wherein [characterized in that the mutation or] mutations are located in both alleles of the *POLG* gene in the trinucleotide (CAG) microsatellite repeat of the *POLG* gene.

5. (currently amended) A method of claim 1, wherein [characterized in that] the at least one mutation in another allele of the *POLG* gene is [or mutations are] located in or near a coding region of the *POLG* gene.

6. (currently amended) A method of claim 2 [[1]], wherein [characterized in that] the at least one mutation [or mutations are located in one allele of the *POLG* gene in the trinucleotide (CAG) microsatellite repeat and another mutation or other mutations in the other allele of the mutant] in another allele of the *POLG* gene is located in or near a coding region of the *POLG* gene.

7. (currently amended) A method of claim 1, wherein [characterized in that] the detection of at least one [[the]] mutation is performed by [using] a gene-technological method.

8. (currently amended) A method of claim 7, wherein [characterized in that] the detection of at least one [[the]] mutation [or mutations] is performed [using] by a gene-technological method selected from the group consisting of the polymerase chain reaction (PCR) or other thermal cycler-based DNA synthetic techniques, molecular cloning in a plasmid or other suitable vector, detection of length variants in a DNA sample by agarose or polyacrylamide gel electrophoresis, gel or capillary electrophoresis and analysis of products tagged with a fluorescent or other label incorporated into the DNA, DNA sequence determination and any heteroduplex-based or similar methods for detecting base mismatches or length variants.

9. (currently amended) A method of claim 1, wherein [characterized in that] the detection of at least one [[the]] mutation [or mutations] is performed by [using] an

immunological method selected from the group consisting of [, such as a] Western analysis, immunohistology and [[or]] immunoassay, for characterization of a mutant gene or gene product.

10. (currently amended) A method of claim 9, wherein [characterized in that] the detection of at least one mutation [or mutations] is performed using immunohistology.

11. (withdrawn) A use of a mutant form of the *POLG* gene encoding the catalytic subunit of mitochondrial DNA polymerase for the diagnosis or prediction of male infertility.

12. (withdrawn) A use of a mutant form of the *POLG* gene encoding the catalytic subunit of mitochondrial DNA polymerase as a diagnostic agent.

13. (withdrawn) A diagnostic kit, characterized in that it comprises reagents capable of identifying the presence or absence of a mutation or mutations in the *POLG* gene encoding the catalytic subunit of mitochondrial DNA polymerase.

14. (withdrawn) A use of the *POLG* gene as an indicator of other pathological conditions associated with or related to male infertility, including those manifesting in women.

Kindly enter the following new claims.

15. (new) A method of claim 2, wherein detection of at least one mutation is performed by a gene-technological method.

16. (new) A method of claim 15, wherein the detection of at least one mutation is performed by a gene-technological method selected from the group consisting of the polymerase chain reaction (PCR) or other thermal cyclers-based DNA synthetic techniques, molecular cloning in a plasmid or other suitable vector, detection of length variants in a DNA sample by agarose or polyacrylamide gel electrophoresis, gel or

capillary electrophoresis and analysis of products tagged with a fluorescent or other label incorporated into the DNA, DNA sequence determination and any heteroduplex-based or similar methods for detecting base mismatches or length variants.

17. (new) A method of claim 2, wherein the detection of at least one mutation is performed by an immunological method selected from the group consisting of Western analysis, immunohistology and immunoassay, for characterization of a mutant gene or gene product.

18. (new) A method of claim 17, wherein the detection of at least one mutation is performed by immunohistology.

19. (new) A method of claim 1, wherein at least one mutation of the *POLG* gene is detected with polymerase chain reaction (PCR) or other thermal cycler-based DNA synthetic techniques.

20. (new) A method of claim 2, wherein at least one mutation of the *POLG* gene is detected with polymerase chain reaction (PCR) or other thermal cycler-based DNA synthetic techniques.